FORM PTO-1390 (Modified) (REV 11-98) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371

ATTORNEY'S DOCKET NUMBER	U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR
19141.0039U2	10/018914

INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/US00/16507	15 June 2000	18 June 1999

TITLE OF INVENTION

SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING

APPLICANT(S) FOR DO/EO/US

HATCH, Michael R.

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. ☒ A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c) (2))
   a. ☐ is transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ has been transmitted by the International Bureau.
   c. ☒ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☐ A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. ☒ A copy of the International Search Report (PCT/ISA/210).
8. ☒ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
   a. ☐ are transmitted herewith (required only if not transmitted by the International Bureau).
   b. ☐ have been transmitted by the International Bureau.
   c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
   d. ☒ have not been made and will not be made.
9. ☐ A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
10. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
11. ☐ A copy of the International Preliminary Examination Report (PCT/IPEA/409).
12. ☐ A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 13 to 20 below concern document(s) or information included:

13. ☐ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
14. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
15. ☒ A **FIRST** preliminary amendment.
16. ☐ A **SECOND** or **SUBSEQUENT** preliminary amendment.
17. ☐ A substitute specification.
18. ☐ A change of power of attorney and/or address letter.
19. ☒ Certificate of Mailing by Express Mail
20. ☒ Other items or information:

Written Opinion
PTO-2038 Credit Card Payment Form in the amount of $1,104.00
Return Postcard

EL924206057US

531 Rec'd PCT 18 DEC 2001

U.S. APPLICATION NO. (IF KNOWN, SEE 37 CFR)	INTERNATIONAL APPLICATION NO.	ATTORNEY'S DOCKET NUMBER
10/018914	PCT/US00/16507	19141.0039U2

21. The following fees are submitted:.

BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :

		CALCULATIONS PTO USE ONLY
☐	Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2) paid to USPTO and International Search Report not prepared by the EPO or JPO **$1,000.00**	
☒	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but Internation Search Report prepared by the EPO or JPO **$860.00**	
☐	International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO **$710.00**	
☐	International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) **$690.00**	
☐	International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**	
	ENTER APPROPRIATE BASIC FEE AMOUNT =	**$890.00**
	Surcharge of **$130.00** for furnishing the oath or declaration later than ☐ 20 ☒ 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).	**$130.00**

CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE	
Total claims	17 - 20 =	0	x $18.00	**$0.00**
Independent claims	4 - 3 =	1	x $84.00	**$84.00**
Multiple Dependent Claims **(check if applicable)**.			☐	**$0.00**

TOTAL OF ABOVE CALCULATIONS =		**$1,104.00**
Reduction of 1/2 for filing by small entity, if applicable. Verified Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28) **(check if applicable)**.	☐	**$0.00**
SUBTOTAL =		**$1,104.00**
Processing fee of **$130.00** for furnishing the English translation later than ☐ 20 ☐ 30 months from the earliest claimed priority date (37 CFR 1.492 (f)). +		**$0.00**
TOTAL NATIONAL FEE =		**$1,104.00**
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31) **(check if applicable).**	☐	**$0.00**
TOTAL FEES ENCLOSED =		**$1,104.00**
	Amount to be: refunded	$
	charged	$

☐ A check in the amount of to cover the above fees is enclosed.

☐ Please charge my Deposit Account No. in the amount of to cover the above fees.
A duplicate copy of this sheet is enclosed.

☒ The Commissioner is hereby authorized to charge any fees which may be required, or credit any overpayment to Deposit Account No. **14--0629** A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO:

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Atlanta, Georgia 30303

SIGNATURE

Jennifer P. Medlin
NAME

41,385
REGISTRATION NUMBER

12/18/01
DATE

ATTORNEY DOCKET NO. 19141.0039U2
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of	
HATCH	
	Group Art Unit: Unassigned
Serial No. Unassigned	
	Examiner: Unassigned
Filed: Herewith	
FOR: **"SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING"**	

PRELIMINARY AMENDMENT

Commissioner for Patents
Box PCT (IPEA/EP)
Washington, D.C. 20231

NEEDLE & ROSENBERG, P.C.
Suite 1200, The Candler Building
127 Peachtree Street, N.E.
Atlanta, Georgia 30303-1811

December 18, 2001

Sir:

Prior to the issuance of an Office Action pertaining to the above-identified patent application, please enter the following preliminary amendment and consider the following remarks.

IN THE SPECIFICATION

On page 1 of the specification, before the first paragraph, please insert the following:

-- The present application is a 35 U.S.C. § 371 national phase application from, and claims

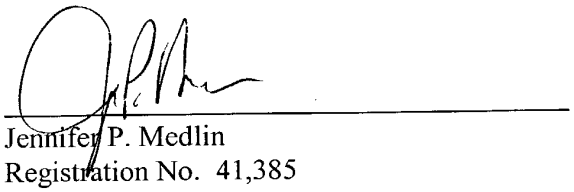
priority to, international application PCT/US00/16507, filed June 15, 2000 (published under PCT Article 21(2) in English), which claims priority to U.S. Utility Application No. 09/357,471, filed 20 July 1999, U.S. Utility Application No. 09/357,452, filed 20 July 1999, and U.S. Provisional Application No. 60/139,943, filed June 18, 1999, which applications are hereby incorporated herein in their entirety.--

REMARKS

The specification is amended herein to update the priority claim for this application. It is believed that no new matter has been added by this amendment, and applicants respectfully request entry of same into the present application.

No fee is believed due; however, the Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 14-0629.

Respectfully submitted,



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ATTORNEY DOCKET NO. 19141.0039U2

CERTIFICATE OF EXPRESS MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, No. EL924206057US an envelope addressed to: BOX PCT (IPEA/EP), Commissioner for Patents, Washington, D.C. 20231, on the date shown below.

Erick Calderon

12/18/01
Date

SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING

This application claims priority to U.S. Provisional Application No. 60/139,943, filed June 18, 1999, the entirety of which is incorporated herein by reference.

BACKGROUND OF THE INVENTION

The present invention is directed to glucose monitoring, and more particularly to the use of continuous glucose measurements for personal fitness management.

Research and development efforts are being made to provide technology that makes glucose monitoring less invasive and disruptive to an individual's daily life. Some systems involve the use of implantable sensor devices, which have drawbacks such as the need for surgery to implant the sensor and the associated risks of infection. Another type of system is much less invasive and involves collecting on a continual basis biological fluid from small openings made in the skin. Such a system is disclosed in co-pending PCT Application No. PCT/US99/16378, filed July 20, 1999, and entitled "System and Method for Continuous Analyte Monitoring." This type of system is proving to be more promising for use on a large scale basis.

The ability to automatically continuously or repeatedly monitor glucose levels of an individual over extended periods of time during an individual's normal daily routine makes it possible to monitor metabolic activity. In particular, monitoring glucose level on a continual basis provides insight into eating habits that lead to weight (gain or loss) management, and into fitness performance.

SUMMARY OF THE INVENTION

The present invention is directed to a system and method for using glucose measurements obtained from an individual on a continuous basis to manage an individual's weight gain or loss and exercise or fitness performance.

In accordance with one embodiment of the invention, a system and method are provided to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level.

In accordance with another embodiment, a system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a desired level or threshold; and generating an indicator when the glucose level during physical exercise is below the threshold level.

The above and other objects and advantages of the present invention will become more readily apparent when reference is made to the following description taken in conjunction with the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a block diagram of a system according to the present invention.

FIG. 2 is a diagram of a fluid collection and sensor device useful in connection with the present invention.

FIG. 3 is a flow chart depicting a weight management process according to an embodiment of the invention.

FIG. 4 is a flow chart depicting a fitness management process according to an embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

FIG. 1 illustrates a glucose monitoring system 100 comprising a tissue-mounted fluid collection and assay device 110 and a monitoring device 150. The fluid collection and assay device 110 is coupled to the monitoring device 150 by a wired link 120 or a wireless link 130. An example of a monitoring system suitable for

use in conjunction with the present invention is the monitoring system disclosed in the aforementioned co-pending PCT Application No. PCT/US99/16378, the entirety of which is incorporated herein by reference. Other examples of fluid collection and sensor devices are disclosed in co-pending PCT Application No. PCT/US99/16226, filed July 20, 1999, and entitled "System and Method for Fluid Management in a Continuous Fluid Collection and Sensor Device," and in PCT Application No. PCT/US00/09393, filed April 7, 2000, and entitled "Assay Device for Measuring Characteristics of a Fluid on a Continual Basis."

With reference to FIG. 2, the fluid collection and assay device 110 is positioned on the tissue proximate to one or more openings 180 made in the tissue to collect biological fluid, such as blood or interstitial fluid. The openings in the tissue may be made by any suitable technique and apparatus known in the art, such as lancet, needle, micro-needle, thermal microporation, etc. An example of a thermal microporation technique is disclosed in U.S. Patent No. 5,885,211. Vacuum may be applied to the fluid collection and assay device 110 from the monitoring device 150 via a conduit 190 to draw fluid from the tissue on a periodic or continuous basis when it is desired to make a reading. Conduit 190 may contain the wired link 120 (FIG. 1). When biological fluid is drawn into the device 110, it contacts an assay element 112 in the fluid collection and assay device 110. The assay element 112 may be any type of glucose assay element known in the art, such as an electrochemical bio-sensor, optically read sensor, etc. Readings are made from the assay element 112 by the monitoring device 150, either electrically via electrodes disposed in or on the assay element 112, or optically. Further details about a fluid collection and assay device 110 are disclosed in the aforementioned PCT applications. An advantage of the continuous analyte monitoring system and methods disclosed in these related applications is the ability to extract and analyze new samples of biological fluid from the same tissue openings over an extended period of time, such as throughout an entire day, several days or longer.

Referring back to FIG. 1, the monitoring device 150 comprises a processor 160 suitable for performing calculations on the readings taken from the assay element in the fluid collection and assay device to derive measurements, such as glucose measurements. The processor 160 may be a microprocessor, application specific integrated circuit (ASIC), digital signal processor, or any other device capable of performing computations necessary for the processes of the present invention.

In one form, the processor 160 is a microprocessor that executes one or more programs stored in a memory 162. Memory 162 is any type of a read only memory (ROM), random access memory (RAM) or a combination thereof suitable for storing a program that contains the instructions for the processes described herein, as well as storing data obtained from measurements and other information derived from that data. One program that may be made available to the processor 160 is a weight loss control program 170 and another is a physical fitness training program 172. These programs may be based on separate instructions or derived from a common set of instructions.

The monitoring device 150 optionally includes a user interface 164 to enable input of information from a user. The user interface 164 is, for example, an alphanumeric keypad, a touch-screen user interface, voice recognition interface, handwriting recognition interface, etc. Programming of parameters into the monitoring device 150 may also be achieved via the user interface 164. A display 166 is also optionally provided to display information such as glucose levels, status information, information being input into the monitoring device by a user, and other messages or information communications from the monitoring device 150 to the user.

The human body produces glucose for nourishment of cells. When production of glucose varies, excess glucose is converted into fat for storage, or the fat is metabolized to produce glucose when glucose levels are low. It is on this principle that the present invention is based. These production mechanisms and rates can be monitored using a continuous glucose monitoring system such as the one shown in FIG. 1. Monitoring glucose levels can provide insight into foods and eating habits,

which lead to weight gain and loss, as well as to energy level and consumption rates in physical exercise.

According to one aspect of the invention, glucose levels are monitored on a continual basis to aid in the selection of nutritional consumption by providing a mechanism to monitor the results of consumption. The impact of certain foods in a particular individual can be assessed by monitoring the amount and rate of glucose produced. Guidelines can be set to achieve desired and controlled weight gain or loss. Similarly, according to another aspect of the invention, by monitoring a person during exercise, the type, rate and duration of the exercise can be assessed based on the glucose consumption and production amounts and rates. Through long term monitoring of changes in these conditions, information can be created to optimize a person's fitness endurance and performance.

Turning to FIG. 3 in conjunction with FIG. 1, a process is shown for a weight management program such as that shown at reference numeral 170 in FIG. 1. In step 200, a maximum desired glucose level is set. This level may be derived by a trained professional (such as a physician) from physical characteristics including body mass index and percentage body fat, and an individual's goals for weight loss or gain. A numeric value corresponding to this maximum level is stored in the weight management program. The storage mechanism may be via an infra-red, radio frequency, or other wireless programming technique to convey information to the monitoring device 150. Alternatively, a keypad or touch-screen is provided on the housing of the monitoring device 150 that allows user or physician access to program the monitoring device 150.

Next, in step 210, the monitoring device 100 records glucose levels at programmed times during the course of a day. For example, the monitoring device 150 will obtain and record readings 288 times a day (every 5 minutes). The number of readings taken may vary so long as readings are taken before and after every anticipated meal event for that user. In step 220, a user logs meal events into the monitoring device 150. The mechanism for logging meal events may be by actuating

a button on the monitoring device 150, triggering a command via wireless, voice or audio command, or any other action via the user interface 164. Moreover, the monitoring device 150 may be responsive to a logging event to initiate several readings at various timed intervals to be sure to obtain sufficient data around the meal event. It is particularly important to obtain sufficient readings after the meal event.

In step 230, the post meal glucose levels are compared with the maximum glucose level. When and if a post meal glucose level exceeds the maximum level, in step 240 the monitoring device 150 may generate an alert indicator that is audio, visual or any combination. In addition, the processor 160 stores an indication of the fact that the maximum level was exceeded. By keeping track of when the maximum glucose level is exceeded, the user may adjust a meal plan or eating habits in step 250. For example, the user may try eating other types of foods or combinations of foods to achieve a lower intake of simple sugars at a particular meal event. The process is repeated from step 210 for a new or modified meal. Also, the maximum glucose level may be adjusted if necessary after sufficient information is learned about the individual. Moreover, the maximum glucose level can be used as a target to achieve as part of a process to achieve weight gain for a particular user.

One method of enabling the user to keep track of the various foods eaten at each meal is through user interaction with the monitoring device 150 and additional intelligence provided in the monitoring device 150. In step 220, when a user logs a meal event, or at any other time convenient to the user, the user may enter information into the monitoring device 150 via the user interface 164 that identifies each food item ingested for a meal event. In this manner, the monitoring device 150 can track which item or items may be contributing to a high glucose reading and inform the user accordingly to assist the user in modifying food selection accordingly to prevent glucose levels from going above the maximum glucose level. This may be achieved through a program and database stored in the monitoring device 150 that is capable of identifying those food items most likely to contain high levels of simple sugars. Moreover, when a user informs the monitoring device 150 of the food items for a

particular meal, the monitoring device 150 may suggest to the user lower quantities of a particular food item if that item was one eaten by the user at that meal, or perhaps suggest other food items known to have less impact on glucose levels. Communication of information from the monitoring device 150 to the user may be in the form of an alphanumeric message or synthesized voice message generated by the processor 160 and displayed on the display 166. This type of communication between the monitoring device 150 and the user may occur during step 250 or any other time when the user may inquire of the monitoring device 150 of eating plans or suggestions.

Referring to FIG. 4 in conjunction with FIG. 1, a process for managing fitness exercise or training will be described. In step 300, glucose levels are recorded to a user's fitness routine or exercise circuit. The monitoring system 100 shown in FIG. 1 is suitable to be worn by a user during nearly any type of physical activity. When a user is about to begin an exercise of fitness activity, a command is given to the monitoring device 150 to initiate the fitness management program so that glucose measurements are taken at appropriate time intervals during the fitness event. The number and frequency of the measurements may vary depending on the duration of the fitness event.

A threshold glucose level is computed in step 310 based on the measurements taken in step 300. The threshold is a goal or desired level and is physiologically dependent on the individual. For example, it may be 10 mg/dL below a fasting glucose level for an individual.

Once the threshold glucose level is computed, in step 320 the user begins his/her fitness routine or exercise circuit and glucose levels are recorded at appropriate time intervals during the fitness event. The monitoring device 100 compares the recorded glucose levels with the threshold level. The monitoring device 100 generates an indication when the glucose level during the fitness event is below the threshold level. The monitoring device 100 may generate (audio, visual or a combination thereof) alerts during the fitness event when the user's glucose level

drops below the threshold level. Alternatively, or in addition to the alerts, the monitoring device may generate historical data summary reports that can be viewed on a personal computer, on a display of the monitoring device itself, or sent to a printer for hard copy. The historical data summary report will indicate when (in time and/or during certain exercises) during the fitness event the glucose level dropped below the threshold level. With this information, the user may modify the exercise routine in step 350 to prevent such a glucose drop. For example, the user may modify the intensity, duration and/or type of exercise in order to maintain sufficient glucose levels, thereby preventing overexertion and/or reduction of muscle mass. Moreover, extended glucose monitoring can help a user determine which foods support extended level glucose periods during exercise. The user may enter information into the monitoring device that describes the type of foods ingested at a meal event. Interaction between the user and the monitoring device similar to that described above in conjunction with the weight management program may also be used in the fitness management program.

The above description is intended by way of example only.

Claims:

1. A method for assisting an individual in weight management, comprising steps of:

setting a maximum desired glucose level for an individual;

recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and

comparing post meal glucose levels with the maximum desired glucose level.

2. The method of claim 1, and further comprising the step of generating an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.

3. The method of claim 2, and further comprising the step of generating a indicator or signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.

4. The method of claim 1, and further comprising the step of receiving input from the individual indicating the occurrence of a meal event.

5. The method of claim 1, and further comprising informing the individual of a food item for a meal event that may be responsible for higher glucose levels.

6. A system for monitoring glucose levels of an individual to assist in weight management, comprising:

a sensor that detects glucose in biological fluid obtained from an individual;

a processor coupled to the sensor, the processor being operative to:

store data representing a maximum glucose level for an individual;

store data representing glucose levels determined from the sensor at multiple times during a day so as to obtain glucose levels after at least one meal event of the individual; and

compare post meal glucose levels with the maximum glucose level.

7. The system of claim 6, wherein the processor generates an indicator when it is determined that a post meal glucose level exceeds the maximum glucose level.

8. The system of claim 6, wherein the processor generates a signal that advises the individual to alter eating habits so as to prevent glucose levels from going above the maximum glucose level.

9. The system of claim 6, wherein the processor generates information to inform the individual of a food item for a meal event that may be responsible for higher glucose levels.

10. A method for assisting an individual in fitness training or exercise, comprising steps of:

recording glucose levels of an individual while the individual is undergoing physical exercise;

comparing glucose levels during physical exercise with a threshold level; and

generating an indicator when the glucose level during physical exercise is below the threshold level.

11. The method of claim 10, and further comprising the step of modifying physical exercise intensity, duration and or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

12. The method of claim 10, and further comprising the step of modifying eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

13. The method of claim 10, and further comprising the step of determining the threshold level based upon glucose levels recorded during physical exercise and a physiologically dependent goal.

14. A system for monitoring glucose levels of an individual to assist in fitness training or exercise, comprising:

a sensor that detects glucose in biological fluid obtained from an individual;

a processor coupled to the sensor, the processor being operative to:

store data representing glucose levels determined from the sensor during periods of physical exercise of the individual;

compare glucose levels during the physical exercise with a threshold level; and

generate an indicator when the glucose level during physical exercise is below the threshold level.

15. The system of claim 14, wherein the processor generates a signal advising the individual to modify physical exercise intensity, duration and/ or selection such that glucose levels substantially throughout the period of physical exercise are at or above the threshold level.

16. The system of claim 14, wherein the processor generates a signal advising the individual to modify eating habits to achieve glucose levels that are at or above the threshold level substantially throughout the period of physical exercise.

17. The system of claim 14, wherein the processor determines a threshold glucose level based on glucose levels recorded during physical exercise and a desired physiologically dependent goal of the individual.

(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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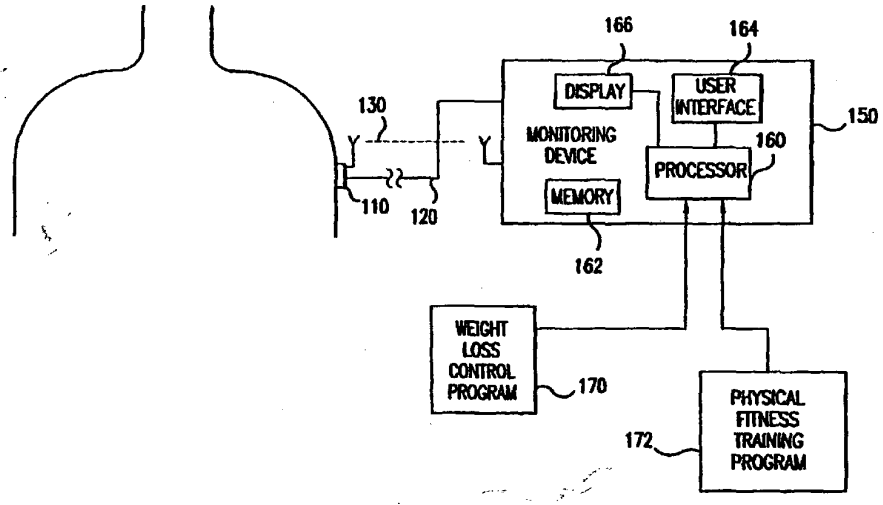
(84) Designated States *(regional)*: ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published:
— *With international search report.*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: SYSTEM AND METHOD FOR MONITORING GLUCOSE TO ASSIST IN WEIGHT MANAGEMENT AND FITNESS TRAINING



(57) Abstract: A system and method to manage an individual's weight by setting a maximum desired glucose level for an individual; recording glucose levels at multiple times during a day for the individual so as to obtain glucose levels after at least one meal event of the individual; and comparing post meal glucose levels with the maximum desired glucose level. A system and method are provided to assist an individual in fitness training or exercise, comprising recording glucose levels of an individual while the individual is undergoing physical exercise; comparing glucose levels during physical exercise with a threshold level; and generating an indicator when the glucose level during physical exercise is below the threshold level.

WO 00/78208 A1

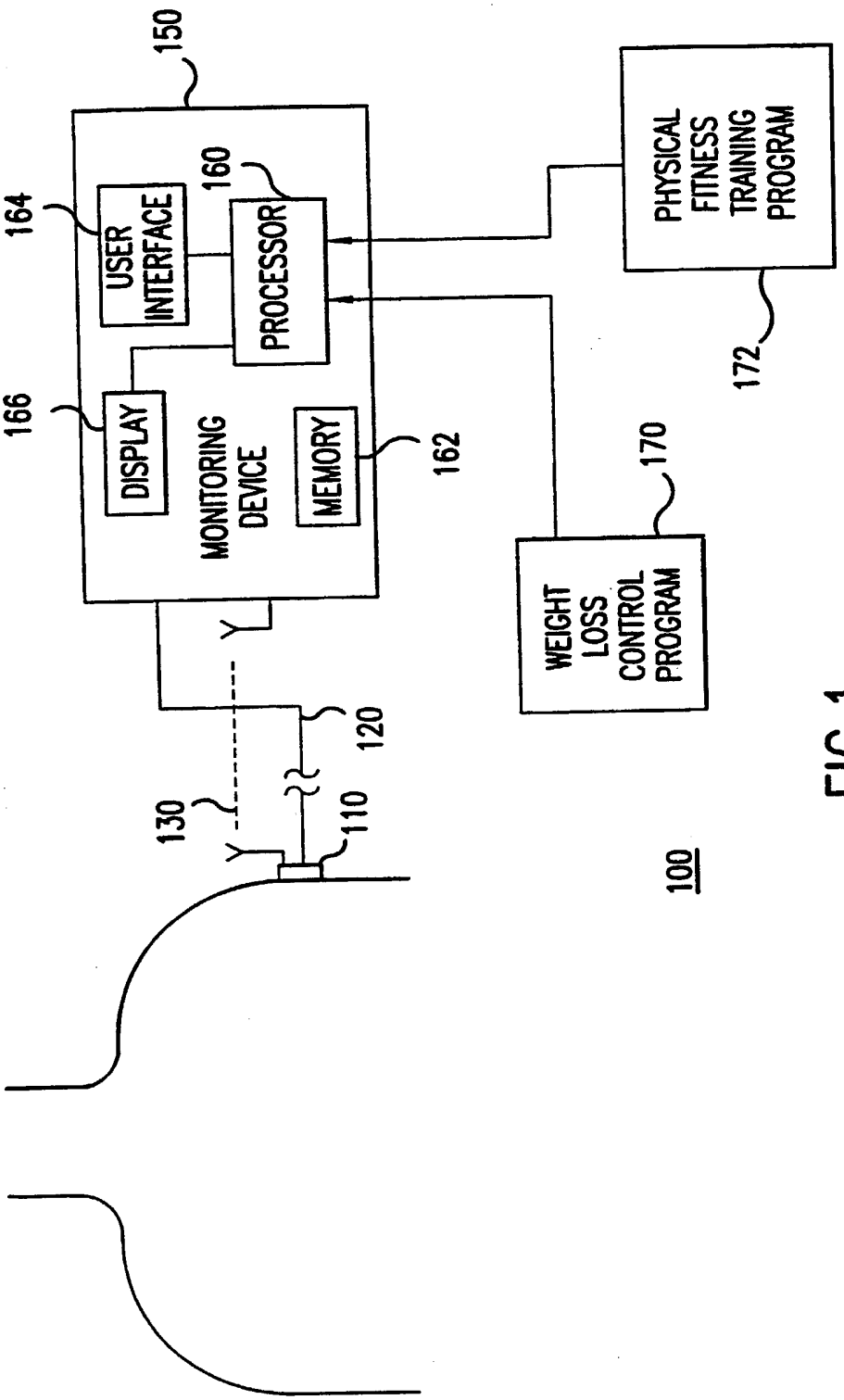

150
164
USER INTERFACE
160
PROCESSOR
PHYSICAL FITNESS TRAINING PROGRAM
172
166
DISPLAY
MONITORING DEVICE
MEMORY
162
170
WEIGHT LOSS CONTROL PROGRAM
Y
120
130
110
Y
100

FIG.1

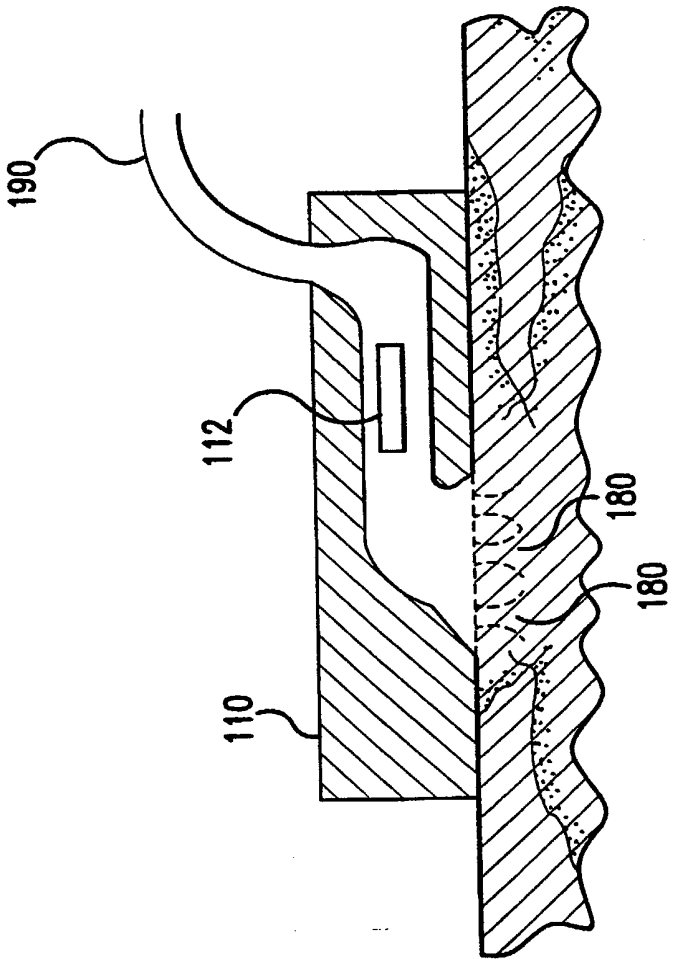


FIG.2

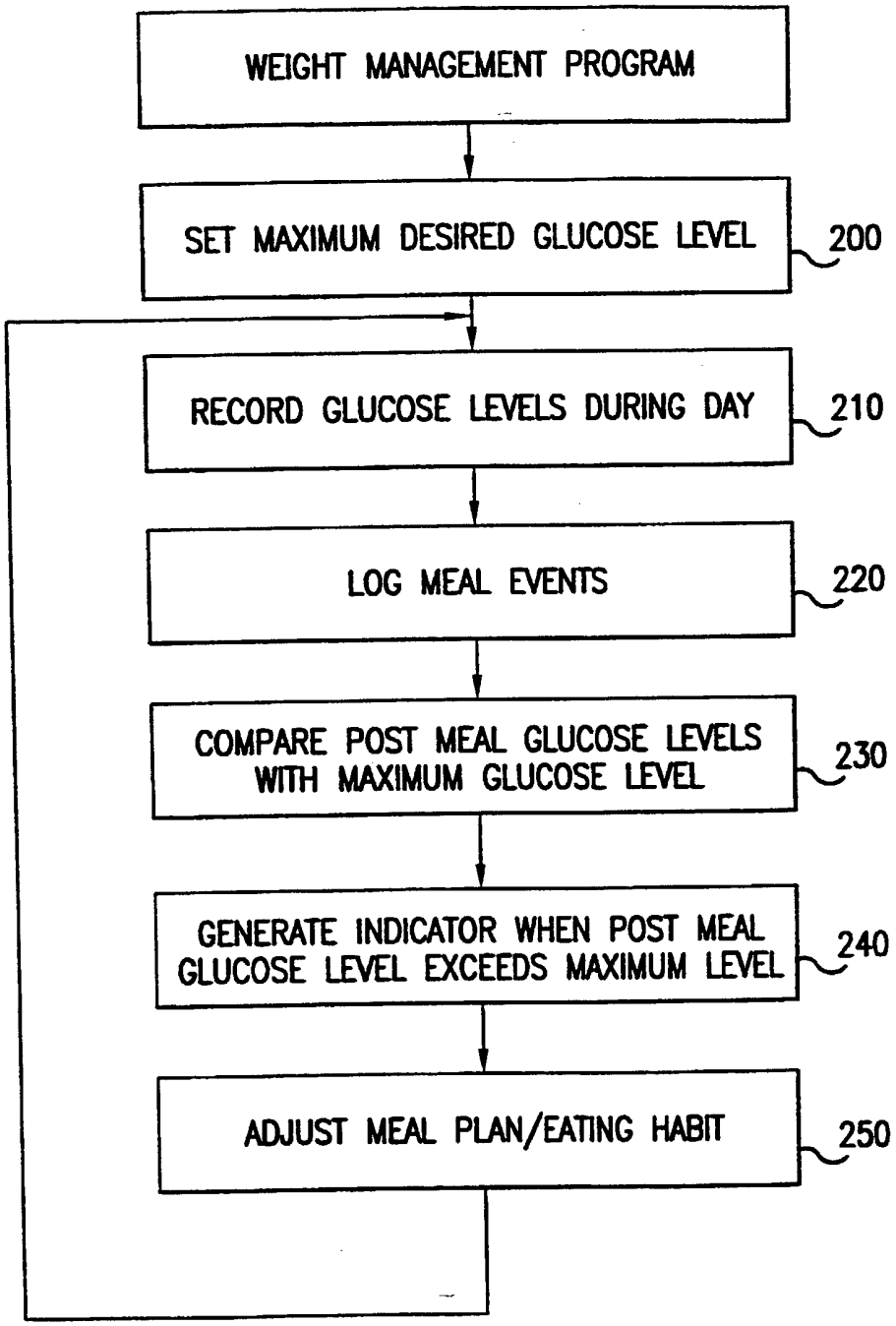

WEIGHT MANAGEMENT PROGRAM
SET MAXIMUM DESIRED GLUCOSE LEVEL
200
RECORD GLUCOSE LEVELS DURING DAY
210
LOG MEAL EVENTS
220
COMPARE POST MEAL GLUCOSE LEVELS WITH MAXIMUM GLUCOSE LEVEL
230
GENERATE INDICATOR WHEN POST MEAL GLUCOSE LEVEL EXCEEDS MAXIMUM LEVEL
240
ADJUST MEAL PLAN/EATING HABIT
250

FIG.3

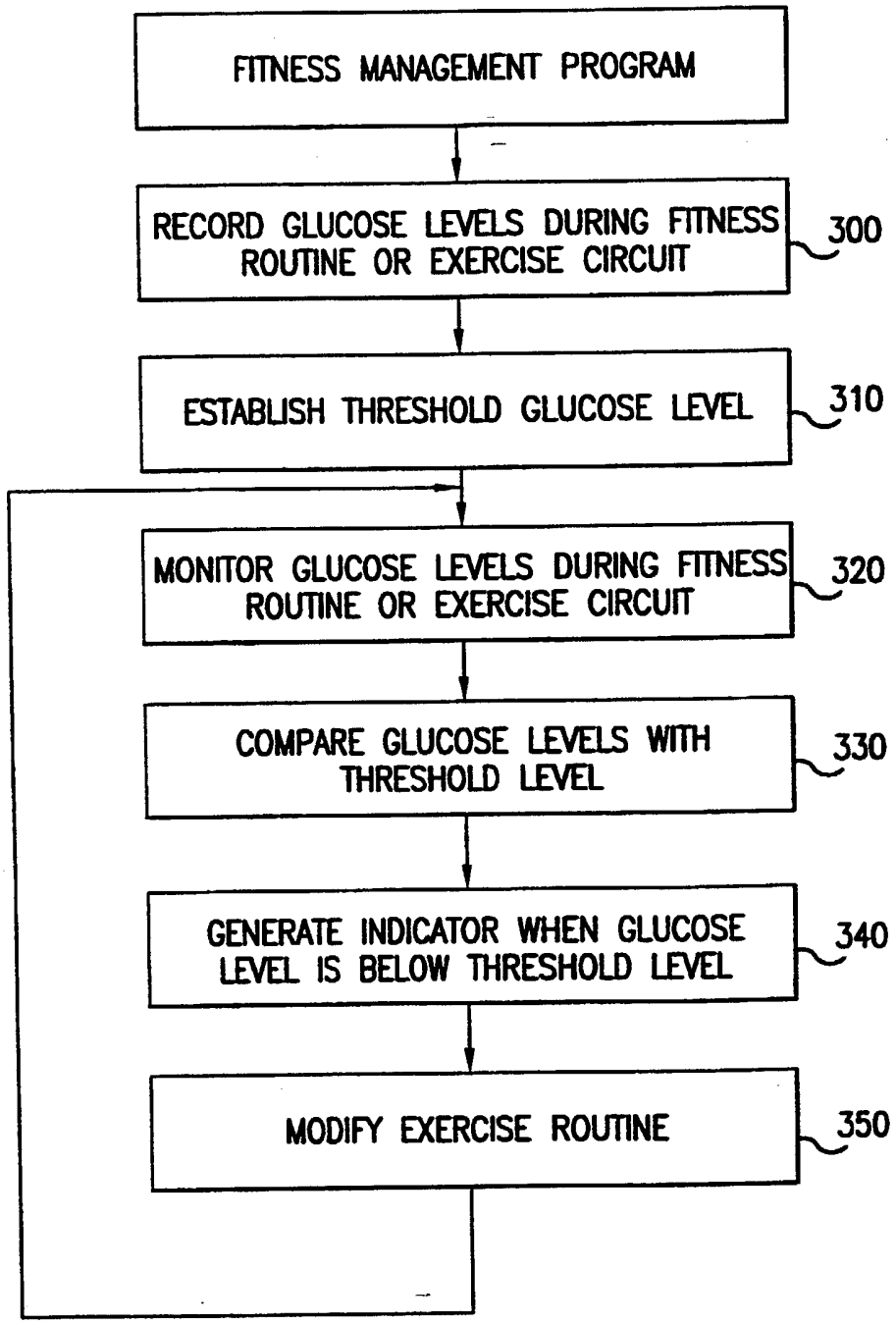

FITNESS MANAGEMENT PROGRAM
RECORD GLUCOSE LEVELS DURING FITNESS ROUTINE OR EXERCISE CIRCUIT
300
ESTABLISH THRESHOLD GLUCOSE LEVEL
310
MONITOR GLUCOSE LEVELS DURING FITNESS ROUTINE OR EXERCISE CIRCUIT
320
COMPARE GLUCOSE LEVELS WITH THRESHOLD LEVEL
330
GENERATE INDICATOR WHEN GLUCOSE LEVEL IS BELOW THRESHOLD LEVEL
340
MODIFY EXERCISE ROUTINE
350

FIG.4

Attorney Docket No. 60055.0002USWO

MERCHANT & GOULD P.C.

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and sole inventor (if only one name is listed below) or a joint inventor (if plural inventors are named below) of the subject matter which is claimed and for which a patent is sought on the invention entitled: System and Method for Monitoring Glucose to Assist in Weight Management and Fitness Training

The specification of which
a. ☐ is attached hereto
b. ☒ was filed on December 18, 2001 as application serial no. 10/018,914 and was amended on (if applicable) (in the case of a PCT-filed application) described and claimed in international no. PCT/US00/16507 filed June 15, 2000 and as amended on (if any), which I have reviewed and for which I solicit a United States patent.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I hereby claim foreign priority benefits under Title 35, United States Code, § 119/365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

a. ☐ no such applications have been filed.
b. ☒ such applications have been filed as follows:

FOREIGN APPLICATION(S), IF ANY, CLAIMING PRIORITY UNDER 35 USC § 119			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)
ALL FOREIGN APPLICATION(S), IF ANY, FILED BEFORE THE PRIORITY APPLICATION(S)			
COUNTRY	APPLICATION NUMBER	DATE OF FILING (day, month, year)	DATE OF ISSUE (day, month, year)

I hereby claim the benefit under Title 35, United States Code, § 120/365 of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, § 1.56(a) which occurred between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. APPLICATION NUMBER	DATE OF FILING (day, month, year)	STATUS (patented, pending, abandoned)
PCT/US00/16507	15/06/2000	Pending
09/357,471	20/07/1999	Pending
09/357,452	20/07/1999	Pending

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below:

U.S. PROVISIONAL APPLICATION NUMBER	DATE OF FILING (Day, Month, Year)
60/139,943	18/06/99

[redacted]

I acknowledge the duty to disclose information that is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (reprinted below):

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim;

or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.

(e) In any continuation-in-part application, the duty under this section includes the duty to disclose to the Office all information known to the person to be material to patentability, as defined in paragraph (b) of this section, which became available between the filing date of the prior application and the national or PCT international filing date of the continuation-in-part application.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Ali, M. Jeffer	Reg. No. 46,359
Altera, Allan G.	Reg. No. 40,274
Anderson, Gregg I.	Reg. No. 28,828
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Beard, John L.	Reg. No. 27,612
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Peterson, Kyle T.	Reg. No. 46,989
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Pytel, Melissa J.	Reg. No. 41,512
Qualey, Terry	Reg. No. 25,148
Randall, Joshua N.	Reg. No. 50,719
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Reiland, Earl D.	Reg. No. 25,767
Rieth, Damon A.	Reg. No. P-52,167
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Trembath, Jon R.	Reg. No. 38,344
Tunheim, Marcia A.	Reg. No. 42,189
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Wahl, John R.	Reg. No. 33,044
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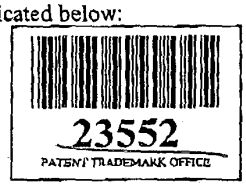
Wong, Bryan A.	Reg. No. 50,836
Wong, Thomas S.	Reg. No. 48,577
Young, Thomas	Reg. No. 25,796
Zeuli, Anthony R.	Reg. No. 45,255

I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/ organization who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Merchant & Gould P.C. to the contrary.

[redacted]

I understand that the execution of this document, and the grant of a power of attorney, does not in itself establish an attorney-client relationship between the undersigned and the law firm Merchant & Gould P.C., or any of its attorneys.
Please direct all correspondence in this case to Merchant & Gould P.C. at the address indicated below:

Merchant & Gould P.C.
P.O. Box 2903
Minneapolis, MN 55402-0903



I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

2 0 1	Full Name Of Inventor	Family Name Hatch	First Given Name Michael	Second Given Name R.
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Signature of Inventor 201: Michael R Hatch			Date: 7/1/02	